

Application No. 10/687,262  
Amendment dated December 21, 2006  
Reply to Office action of June 28, 2006

### REMARKS / ARGUMENTS

#### Claims Currently Pending

Claims 1-16 were pending. Claims 13-16 have been cancelled by amendment herein. Thus, claims 1-12 are now pending.

#### Election / Restrictions

Applicants have, in their reply filed May 31, 2006, elected to prosecute claims directed to the invention of Group II, claims 1-11, 15-16 as they are drawn to a piperidine compound wherein R<sup>2</sup> and R<sup>3</sup> together form a ring.

The claims have been amended herein so that, it is believed, they are no longer directed to piperidines of the formula I wherein R<sup>2</sup> and R<sup>3</sup> do not together form a ring.

The need for further restriction with respect to claims 10 and 11 is believed to be rendered moot by the amendments made in these two claims.

Claim 12 has been amended so that it is now believed to be a proper method claim. It is noted that page 1 of the action does not indicate that claim 12 has been withdrawn from consideration. Accordingly, claim 12 has been treated in the claim listing as a claim that is pending, not withdrawn. To the extent that the examiner does consider claim 12 to be withdrawn it is requested that the claim be rejoined.

The withdrawal from consideration of claims 13 and 14 is rendered moot by their cancellation.

It is believed that all non-elected inventions have been deleted from the claims by the amendments made herein.

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#### Objection to the Specification

The specification has been objected to because the application number does not appear on the first page of the specification.

The basis for this objection and the correction required are, respectfully, not understood. Clarification is requested.

It is believed that there is nothing in the statute or rules which would require that the application number appear on the first page of the specification. It is requested that the Office explain, with appropriate citation to the statute or rules, why the objection to the specification is proper.

#### Claim Objections

The basis for objection to claims 1-12 is believed to be overcome by the amendments made herein. Claims 10-12 have been amended so that they now depend from only claim 1. They are no longer multiple dependent claims.

The objection to claims 15 and 16 is rendered moot by the cancellation of these claims.

The objection to claim 10 that is based upon the inclusion of the recitation “with inorganic or organic acids or bases inorganic or organic acids or bases” is believed to be obviated by deletion of this phrase from the claim as amended.

#### Claim Rejections – 35 USC 101

The basis for rejection of claim 12 under 35 USC 101 is believed to be overcome by the amendment of claim 12 herein. Claim 12, as amended, sets forth a method step and is believed to be a process claim that is compliant with Section 101.

Claim Rejections – 35 USC 112

The basis for rejection of claims 1-11 under 35 USC 112, second paragraph, is believed to be overcome by the amendments made in claims 1-11. Claims 1-9 as amended are now directed to “A compound the formula I”, not “A CGRP antagonist of general formula I”. Claim 10 as amended is now directed to “A physiologically acceptable salt of a compound according to claim 1” and claim 11 as amended is now directed to “A pharmaceutical composition containing a compound according to claim 1”.

The basis for rejection of claim 12 under 35 USC 112, second paragraph, is believed to be overcome by the amendment of claim 12 made herein. Claim 12 as amended recites a method step.

Claims 1-11 stand rejected under 35 USC 112, first paragraph, apparently because the specification is deemed to be not enabling for the production or use of hydrates of the claimed compounds of formula 1 or hydrates of salts of compounds of formula I. This basis for rejection of claims 1-11 is traversed for the following reasons. First, once one has a compound that can form a hydrate, or a salt that can form a hydrate, the actual production of the hydrate is trivial. A person of ordinary skill in the art needs no special teaching to know how to do this. Second, it is respectfully asserted that a hydrate of a compound can generally used therapeutically in essentially the same manner as the compound itself. Changing the hydration state of a compound does not change the chemical structure of the compound. A hydrate is merely an association of a given compound with water. While this association with water may alter the physical properties of the compound it cannot alter the chemical properties of the compound, because the compound is not structurally changed in any way. The action provides no evidence that would support the implicit assertion that the hydrate of a compound would not be expected to have the same therapeutic utility as the compound itself. In short, the action sets forth no cogent reasons why the teachings given by the disclosure respecting how to make and use compounds of formula I and their salts should not be applicable to hydrates of compounds or formula I or to hydrates of these salts.

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The rejection of claims 15 and 16 under 35 USC 112, first paragraph, is rendered moot by the cancellation of these claims.

#### Double Patenting

A. Claims 1-11 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 11/107052 or claims 1-5 of copending Application No. 11/107195 in view of copending Application No. 10/685921. This provisional rejection is traversed for the reasons that follow.

It is respectfully asserted that, in view of the foregoing amendments and arguments, no grounds for rejection remain in the present application, aside from the present obviousness-type double patenting rejections.

Reference is made to the discussion of double patenting rejections in MPEP Section 804, and in particular to the discussion respecting provisional obviousness-type double patenting (ODP) rejections between copending applications having a common owner or assignee.

In this regard, it should be noted that the present application and the three copending applications cited are co-owned.

MPEP Section 804 states as follows:

If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.

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As shown by the table below, the present application is earlier filed than copending 11/107052 and copending 11/107195. Accordingly, and in view of the instruction given by MPEP 804, the Office should withdraw the ODP rejection to the extent that it is predicated upon copending 11/107052 and copending 11/107195.

Application	U.S. Filing or 371(c) Date
10/687,262 (present application)	10/16/2003
11/107052 (copending)	4/15/2005
11/107195 (copending)	4/15/2005
10/685921 (copending)	10/15/2003

The compounds claimed by copending Application No. 10/685921 differ structurally from those claimed in the present application. The claims of copending Application No. 10/685921 encompass compounds wherein the phenyl moiety has two substituents Y and Z. (Note that formula I is depicted incorrectly in claim 1 of 10/685921. It is depicted correctly on page 1 of the application.) By way of contrast, in the claims of the present application the compounds have a phenyl moiety that bears three substituents U, V and W. Copending Application No. 10/685921 has a U.S. filing date that is one day earlier than the present application. It can thus constitute a basis for an ODP rejection, but only if the Office can show why one of ordinary skill in the art would have been motivated to modify the compounds claimed by copending Application No. 10/685921 in order to produce the compounds claimed by the present application. The Office has not produced any such showing. It should be noted that copending 11/107052 and copending 11/107195 cannot be relied upon by the Office as the source for such motivation, because the present application is earlier-filed.

B. Claims 1-11 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/755593 in view of copending Application No. 10/685921. This provisional rejection is traversed for the reasons that follow.

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Again, it is respectfully asserted that, in view of the foregoing amendments and arguments, no grounds for rejection remain in the present application, aside from the present obviousness-type double patenting rejections.

Again, reference is made to the discussion of double patenting rejections in MPEP Section 804, and in particular to the discussion respecting provisional obviousness-type double patenting (ODP) rejections between copending applications having a common owner or assignee.

It should be noted that the present application and the two copending applications cited are co-owned.

As shown by the table below, the present application is earlier filed than copending 10/755593. Accordingly, and in view of the instruction given by MPEP 804, the Office should withdraw the ODP rejection to the extent that it is predicated upon copending 10/755593.

Application	U.S. Filing or 371(c) Date
10/687,262 (present application)	10/16/2003
10/755593 (copending)	1/12/2004
10/685921 (copending)	10/15/2003

The compounds claimed by copending Application No. 10/685921 differ structurally from those claimed in the present application, as explained above. Copending Application No. 10/685921 has a U.S. filing date that is one day earlier than the present application. It can constitute a basis for an ODP rejection, but only if the Office can show why one of ordinary skill in the art would have been motivated to modify the compounds claimed by copending Application No. 10/685921 in order to produce the compounds claimed by the present application. The Office has not produced any such showing. It should be noted that copending 10/755593 cannot be relied upon by the Office as the source for such motivation, because the present application is earlier-filed.

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C. Claims 1-11 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 11/107189 in view of copending Application No. 10/685921. This provisional rejection is traversed for the reasons that follow.

Again, it is respectfully asserted that, in view of the foregoing amendments and arguments, no grounds for rejection remain in the present application, aside from the present obviousness-type double patenting rejections.

Again, reference is made to the discussion of double patenting rejections in MPEP Section 804, and in particular to the discussion respecting provisional obviousness-type double patenting (ODP) rejections between copending applications having a common owner or assignee.

It should be noted that the present application and the two copending applications cited are co-owned.

As shown by the table below, the present application is earlier filed than copending 11/107189. Accordingly, and in view of the instruction given by MPEP 804, the Office should withdraw the ODP rejection to the extent that it is predicated upon copending 11/107189.

Application	U.S. Filing or 371(c) Date
10/687,262 (present application)	10/16/2003
11/107189 (copending)	4/15/2005
10/685921 (copending)	10/15/2003

The compounds claimed by copending Application No. 10/685921 differ structurally from those claimed in the present application, as explained above. Copending Application No. 10/685921 has a U.S. filing date that is one day earlier than the present application. It can constitute a basis for an ODP rejection, but only if the Office can show why one of ordinary

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skill in the art would have been motivated to modify the compounds claimed by copending Application No. 10/685921 in order to produce the compounds claimed by the present application. The Office has not produced any such showing. It should be noted that copending 11/107189 cannot be relied upon by the Office as the source for such motivation, because the present application is earlier-filed.

D. Claims 1-11 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 12-13 of copending Application No. 10/685921 in view of claim 1 of copending Application No. 10/755593. This provisional rejection is traversed for the reasons that follow.

Again, it is respectfully asserted that, in view of the foregoing amendments and arguments, no grounds for rejection remain in the present application, aside from the present obviousness-type double patenting rejections.

Again, reference is made to the discussion of double patenting rejections in MPEP Section 804, and in particular to the discussion respecting provisional obviousness-type double patenting (ODP) rejections between copending applications having a common owner or assignee.

It should be noted that the present application and the two copending applications cited are co-owned.

As shown by the table below, the present application is earlier filed than copending 10/755593. Accordingly, and in view of the instruction given by MPEP 804, the Office should withdraw the ODP rejection to the extent that it is predicated upon copending 10/755593.



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10/687,262 (present application)	10/16/2003
10/755593 (copending)	1/12/2004
10/685921 (copending)	10/15/2003

The compounds claimed by copending Application No. 10/685921 differ structurally from those claimed in the present application, as explained above. Copending Application No. 10/685921 has a U.S. filing date that is one day earlier than the present application. It can constitute a basis for an ODP rejection, but only if the Office can show why one of ordinary skill in the art would have been motivated to modify the compounds claimed by copending Application No. 10/685921 in order to produce the compounds claimed by the present application. The Office has not produced any such showing. It should be noted that copending 10/755593 cannot be relied upon by the Office as the source for such motivation, because the present application is earlier-filed.

#### Summary and Conclusion

It is respectfully asserted that all objections to the specification and claims, and all rejections of the claims have been overcome by the foregoing amendments and/ or arguments. Accordingly, it is urged that the application is now in condition for allowance.

Respectfully submitted,

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